STATE OF NEW YORK
DEPARTMENT OF HEALTH
Flanigan Square 547 River Street Troy, New York 12180-2216

Richard F. Daines, M.D.
Commissioner

James W. Clyne, Jr.
Executive Deputy Commissioner

May 5, 2010

Hon. Edward J. Markey
Chairman, Subcommittee on Energy and Environment
Committee on Energy and Commerce
United States House of Representatives
Washington, D.C. 20515

Dear Chairman Markey:

This letter is in response to your letter to Mr. Steven Gavitt, requesting information regarding New York's regulation of medical use radioactive material. Please note that our regulations on the medical use of ionizing radiation are contained in Part 16 of the New York State Sanitary Code and can be found on our Web site at: www.nyhealth.gov/radiation. Detailed responses to each of the questions contained in your letter are provided in the attached enclosures.

Please be assured that the New York State Department of Health shares your concern for public health and safety. We continue to believe that our regulations for release of patients who have been treated with radioisotopes adequately protect the public from any unacceptable risk.

If you have additional questions, please contact Mr. James Clancy, Assistant Commissioner, Office of Governmental and External Affairs, at (518) 473-1124.

Sincerely,

Howard A. Freed, M.D.
Director
Center for Environmental Health

Enclosures

cc: Mr. Clancy

Question 1:
How many iodine-131 (I-131) licensee facilities are overseen by your State?

The New York State Department of Health (Department) regulates approximately 250 radioactive materials licensees that are authorized to use I-131 where a written order is required (administration of greater than 30 microcuries of I-131 or I-125). Please note that this includes both diagnostic and therapeutic use of Iodine. Also, the New York City Department of Health and Mental Hygeine has jursidiction of medical uses of radioactive materials within the five boroughs of New York City.

Question 2:
How often does your State perform sampling inspections at each of theseI-131 licensee facilities?

Depending on the type of radioactive materials license, routine inspections are performed every two to four years. Facilities authorized for radiation oncology procedures, including I-131 radiopharmaceutical therapy, are inspected every two years; hospitals that are authorized for I-131 radioapharmaceutical therapy are inspected every three years; and private medical practices that only use I-131for diagnostic procedures are inspected every four years.

Question 3:
What does such an inspection entail? Please provide copies of any handbooks or inspection checklists or other similar documents that are used to conduct such inspections.

A radioactive materials inspection typically includes, but is not limited to: reviewing documentation of the radiation protection program to ensure compliance with the regulatory requirements; interviewing individuals who work with radioactive materials; observing activities involving radioactive materials; and performing confirmatory radiation exposure measurements. Enclosed is a form used during inspections.

Question 4:
NCRP 155, includes "Radiation Safety Precautions for Radiopharmaceutical Therapy Patients"[4]. For a patient receiving 175 millicuries of 1-131, the patient is instructed not to hold or embrace children for more than ten minutes a day for 21 days; to refrain from sharing a bed with one's sleeping partner for seven days; and for the first day, to store and launder one's used clothing and bed linens separately from the rest of the household, using two rinse cycles; to wipe down the telephone with paper towels and then discard the paper towels; etc. What instructions has your State given to its medical licensees about how to provide guidance to patients to ensure that these radiation precautions will be followed?

The Department requires its medical licensees to submit a copy of the instructions that will be provided to patients who receive therapy doses of I-131 as outpatients, or who are being discharged after hospitalization for an I-131 treatment. The instructions submitted are reviewed during the license or amendment review process.

Question 5:
In the past ten years, how many times has your State, as part of these inspections, requested documentation from the licensee facilities that details the individualized analysis and/or dose calculations used when determining whether to send a patient that was treated with 1-131 in excess of the default limits home, or to a hotel?

Reviewing release criteria, including exposure rate measurements, patient interview documentation and dose calculations is routinely performed during inspections. We do not track this information.

Question 12:
Has your State ever issued an advisory or guidance warning licensees not to send radioactive patients to hotels: If so, please provide copies.

The Department has determined that issuance of an advisory warning licensees not to send radioactive patients to hotels is not necessary given the regulation's flexibility to be applied to a variety of individual patient situations. The Department believes that the current regulations provide adequate protection to members of the public.

Question 13: Are your licensees required to report to you any instances in which released I-131 patients caused radiation exposure to family members or members of the public?

All nuclear medicine patients emit some radiation. The purpose of the release criteria is to ensure appropriate and conserative estimates are used by the facility before the patient is released so that actual exposures will be below the limit of 5mSv to another individual.

Question 14: Please provide copies of all correspondence, including emails, letters, meeting or telephone notes or other materials between your State and the NRC related to the release of patients that have been treated with radionuclides.

The only correspondence between the NRC and New York State regarding patient release are forwarded copies of the NRC's responses to your requests for information.

Question 15:
Please also provide reports for instances in which documents relating to patient release were found to be missing, inadequate, or unclear during the course of a sampling inspection. If your sampling inspections found that a licensee knew of a patient who went to a hotel after treatment, whether or not by explicit instruction, please provide all documentation relating to those cases.

Facilities that have missing or incomplete documentation for determining compliance with the patient release criteria would be in non-compliance with the requirements and subject to possible enforcement action.